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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,299	10/25/2001	Stewart Thomas Leslie	208.1009	4506

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
08/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/037,299	LESLIE, STEWART THOMAS	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/25/08 & 10/06/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 4/20/10.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 8/25/08 and 10/06/08 were filed in a timely manner. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, and 5-23 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Becher et al (DE 197 43 484 hereafter '484) in view of Porter (USPN 4,175,119 hereafter '119) and Chang (USPN 4,956,171 hereafter '171).

The '484 patent discloses a transdermal therapeutic system (TTS) that comprises a distressing substances that when ingested orally causes a repulsive distressing reaction to the abuser (abstract). The TTS may comprise analgesic medicaments (¶ 2 of translation). The TTS comprises an impermeable backing layer, a medicament layer and a distressing compound layer that does not interact with the medicament during proper use (claims). Alternatively the device can comprise a single reservoir comprising the medicament and distressing substance (¶ 4 of translation). The distressing substance can cause nausea (claims).

The reference differs from the instant claims in that it is silent to the specific distressing compounds of the instant claims as well as the opioid analgesic of the instant claims. However the '484 patent clearly discloses the basic concept of imparting a distressing compound to a compound with a potential for abuse in an effort to deter misuse. The reference clearly suggests that this can be used for drugs with abuse potential. The combination of deterring substances with potent analgesic is well known as seen in the '119 patent.

The '119 patent discloses the use of an emetic to prevent accidental or initial overdose of an active substance (abstract). The active substance includes narcotics such as codeine, hydromorphone and oxycodone (col. 3, lin. 55-57). The emetic compounds which induce vomiting and nausea include emetine HCl, ipecamine, and ipecacuanhin acid (col. 1, lin. 5-58). It would have been obvious to include these specific compounds in to the TTS of the '484 patent since these compounds would solve the same problem.

Regarding the specific opioid analgesics, again the '484 patent is suggestive of analgesic with potential for abuse as being useful in the TTS. The use of opioid analgesic in transdermal dosage forms is well known in the art as seen in the '171 patent.

The 171 patent discloses a transdermal drug delivery system comprising a permeation enhancer (abstract). The system can comprise a reservoir or a matrix laminate adhesive (Figures 1 and 2). For the reservoir the drug is dissolved into a solution with the permeation enhancer and formed into a gel (col. 6, li. 5-55). The matrix materials are blended and spread onto a backing sheet and prepared for application (col. 7, lin. 5-35). The drugs useful in the transdermal device include buprenorphine and hydromorphone (col. 7, lin. 30). It would have been obvious to combine these compounds into the TTS of the '484 since the reference is suggestive of analgesic medicaments.

With these aspects in mind it would have been obvious to combine the prior art in order to provide a composition that deterred improper oral use. The '484 patent discloses a transdermal therapeutic device that combines deterring compounds with medicaments with potential for abuse and misuse that when oral ingested cause nausea and a distressing physiological response. It would have been obvious to include the specific compounds the '119 patent since they solve the same problem. It would have been obvious to include the specific drug compounds of the '171 patent since these abusable compounds are suggested by the '484 patent. One of ordinary skill in the art would have been motivated to combine the emetics of the '119 in order to induce a distressing affect on a potential abuser, trying to misuse the compounds of the '171 patent. This combination would have been obvious with an expected result of a stable formulation that deters abuse.

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 5-23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. The amended claims now preclude the inclusion of all opioid antagonists. This overcomes the Lee patent; however this negative limitation required further search and consideration. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618